Message

From: Abdellatif, Sameh [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DA35B30C2C442A802A940056ED76BB-ABDELLATIF, SAMEH]
Sent: 9/15/2017 3:58:46 PM
To: Hartten, Andrew S [Andrew.S.Hartten@chemours.com]
CC: Dudar, Helen [Helen.Dudar@dep.nj.gov]; Norcross, Scott [scott.norcross@aecom.com]; Migliarino, Maurice [Maurice.Migliarino@dep.state.nj.us]; Conetta, Benny [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995e1ef7b652481d89b51a9913171390-Conetta, Benny]
Subject: RE: Proposed Agenda For Chambers Works September 19th Quarterly Status Meeting
Attachments: Salem Canal Investigation Summary Report 2017.pdf; Delaware River NAPL Delination 2016.pdf

Andrew,

Attached please find EPA & NJDEP comments on the 2017 Salem Canal Investigation Summary Report & the 2016 Delaware River NAPL Delineation Report. it should be noted that additional comments may be forwarded.

Also, we would like to add couple of items to the September 19, 2017 meeting agenda;

1) The current status of the wooden water pipe release issue on Route 48/Game Creek Road.

2) Brief discussion on the extent of PCBs at the site since sediment sample SC-236-OutT2(0.5-1.0), in the Tidal Reach showed 118 ppm total PCBs. "Please see EPA&NJDEP attached comments on the Salem Canal Investigation Report."

Thanks
Sam Abdellatif
Hazardous Waste Programs Branch
Clean Air Sustainability Division
U.S. Environmental Protection Agency, Region 2
290 Broadway, 22nd. Floor
New York, NY 10007-1866
Phone: (212) 637-4103

From: Norcross, Scott [mailto:scott.norcross@aecom.com]
Sent: Thursday, September 14, 2017 11:15 AM
To: Abdellatif, Sameh <Abdellatif.Sameh@epa.gov>; Conetta, Benny <Conetta.Benny@epa.gov>; Seppi, Pat <Seppi.Pat@epa.gov>; Dudar, Helen <Helen.Dudar@dep.nj.gov>
Cc: Hartten, Andrew S <Andrew.S.Hartten@chemours.com>
Subject: Proposed Agenda For Chambers Works September 19th Quarterly Status Meeting

On behalf of Chemours Project Director Andrew Hartten, please review this draft agenda for our meeting next Tuesday in Edison New Jersey. Please let us know if you have additional topics to add to the discussion.

Introductions
Safety Topic
Review Previous Meeting Minutes and follow up items
Project Updates
    Delaware River DNAPL Investigation: report submitted 4/13, comments pending
    Salem Canal: reports submitted 2/21 & 4/12, comments pending
    NJPDES-DGW Permit Renewal:

Occupied Building Investigation:
AOC1 Sheet Pile Barrier
2014 RFI Report
PFAS: CSM report submitted 7/19, comments pending,
PFAS Offsite sampling program
Discussion

Thank You,

Scott Norcross
Senior Project Manager, Environment
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

SEP 15 2017

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. Andrew S. Hartten
Principal Remediation Project Manager
The Chemours Group
1007 Market Street
P.O. Box 2047
Wilmington, DE 19899

Re: 2016 Delaware River NAPL Delineation Report
Chemours Chambers Works, Route 130
Deepwater, Salem County, New Jersey
NJDEP SRP PI# 008221
EPA I.D. No.: NJD 002385730

Dear Mr. Hartten:

The United States Environmental Protection Agency (EPA) Region 2 and the New Jersey Department of Environmental Protection (NJDEP) have completed their review of the 2016 Delaware River NAPL Delineation Report dated April 13, 2017, submitted pursuant to the Resource Conservation and Recovery Act (RCRA) Hazardous and Solid Waste Amendments (HSWA) Permit and the Technical Requirements for Site Remediation at N.J.A.C. 7:26E (Tech Regs). Our comments are as follows.

1. **5.2.1 Equilibrium Partitioning (EqP) Analysis:** The report states that a fractional organic carbon (F_{oc}) value of 0.0005 was selected for sediment within the aquifer and an F_{oc} value of 0.02 was selected for the 0"-12" sediment interval. Chemours should discuss how these levels compare to the empirical data collected during the sampling effort.

2. **5.2.4 Verification of EqP and Summed Organic Constituents (SOC) Evaluation:** The report indicates that in samples D16-BOR-03(5.5-6) and D16-BOR-05(5.0-6.0), NAPL was observed. However, the other lines of evidence did not support the presence of NAPL. Therefore, the NAPL was dismissed.

   Regardless of what other lines of evidence indicates, in accordance with N.J.A.C. 7:26E-2.1(a)14, "either free product or residual product is present in any environmental media using direct observation, enhanced field observation methods, field instrumentation measurements, or laboratory analytical data." Therefore, determination of the presence of free product is not based on the entire weight of evidence. If NAPL is visually observed, then regardless of the other lines of evidence, NAPL is assumed to be present. Please address this.

3. **5.3 Temporal Comparisons:** The report states "that there is minimal difference between the two data sets," for 2009 and 2016.

   However, the mean Freon 113 concentration increased over four-fold and the mean chlorobenzene concentration increased approximately 30%. These data indicate an increasing trend for the period of 2009 to 2016. Please address this.

4. **6.2.1 Northern and Southern Study Area - Shallow Sediment:** See comments under 5.2.1 Equilibrium Partitioning (EqP) Analysis, above. Please address this.

5. **6.2.2 Southern Study Area - B Aquifer:** The report states that "2016 boring D15-BOR-14 did not confirm the previous findings of 2009 boring D15-BOR-08. This is due to the fact that refusal of the sampling device occurred at depths shallower than the deep samples collected at D15-BOR08, so this location is inconclusive."

   Given that the 2016 boring could not duplicate the depth of the 2009 boring, then the NAPL found in 2009 must be assumed to still be present. Please address this. General question. If refusal is encountered is there a process (or SOP) that describes how and where to move off the location to a nearby location so that a boring at the correct depth can be collected? If not, this should be considered in the future.

6. **6.2.3 Northern Study Area - B Aquifer:** The report states that "visual and odor lines of evidence (LOE) were noted in sediment samples collected above the basal DNAPL determinations, but the samples did not contain constituents exceeding the SOC concentration threshold to be considered a DNAPL LOE. Therefore, the middle zones are likely impacted by site constituents, possibly through diffusion or as relic characteristics in sediments that have recovered over time, but DNAPL is believed to not be present."

   As stated in comments on 5.2.4 Verification of EqP and SOC Evaluation, above, visual evidence of NAPL indicates the presence of NAPL, regardless of the other lines of evidence. Please address this.

7. **Appendix D- Boring Logs:** Many of the boring logs (D15-BOR-19, D16-BOR-2, D16-BOR-3, D16-BOR-05) indicate the presence of NAPL based on visual observation.

   As indicated in comments on 5.2.4 Verification of EqP and SOC Evaluation, above, anywhere a visual observation of NAPL is made, NAPL is assumed to be present. Please address this.

8. **Appendix F- Lines of Evidence (LOE) Summary Table:** As indicated in 5.2.4 Verification of EqP and SOC Evaluation and Appendix D - Boring Logs comments above, any sample with visual evidence of NAPL must be considered to contain NAPL, regardless of the other LOEs. Please address this.

9. **Appendix H- Delaware River NAPL Delineation Sampling Plan - Data Gap Phase III:** The data gap plan must take into account all sample locations where visual evidence of NAPL was present. Please revise the sampling plan.

Additional comment by Ecological Risk Assessor

The entire weight of evidence is not needed to determine the presence of free or residual product (See N.J.A.C. 7:26E-2.1(a)14). Specifically, NJDEP considers visual observation of NAPL (independent of other lines-of-evidence) as confirmation of the presence of NAPL.

In consideration of the above, the Delaware River NAPL Delineation Sampling Plan — Data Gap Phase III presented in Appendix H must re-evaluate the extent of additional sampling necessary to fully delineate NAPL under the Delaware River. The area west of D15-BOR-16 and the area northeast of E16-BOR-05 are examples where NAPL was visually observed and further delineation is necessary (see Figure 1 of Appendix H). Please revise the sampling plan.

Please submit a written response addressing the above comments within sixty (60) days of your receipt of this letter. We are prepared to discuss the above comments prior to the submittal of a response letter.

If you have any questions, please call Sam Abdellatif, of my staff, at (212) 637-4103.

Sincerely yours,

Ben Conetta, Chief
Corrective Action Section
Hazardous Waste Programs Branch

cc: Helen Dudar, NJDEP-BCM

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

SEP 14 2017

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. Andrew S. Hartten
Principal Remediation Project Manager
The Chemours Group
1007 Market Street
P.O. Box 2047
Wilmington, DE 19899

Re: 2017 Salem Canal Investigation Summary Report
Chemours Chambers Works, Route 130
Deepwater, Salem County, New Jersey
NJDEP SRP PI# 008221
EPA I.D. No.: NJD 002385730

Dear Mr. Hartten:

The United States Environmental Protection Agency (EPA) Region 2 and the New Jersey Department of Environmental Protection (NJDEP) have completed their review of the February 21, 2017 Salem Canal Summary Investigation Report, submitted pursuant to the Resource Conservation and Recovery Act (RCRA) Hazardous and Solid Waste Amendments (HSWA) Permit and the Technical Requirements for Site Remediation at N.J.A.C. 7:26E (Tech Regs). Our comments are as follow.

Reporting Units
The tables and figures report sediment results in mg/kg, µg/kg and pg/g. All sediment results, with the exception of PFAS, should be reported in mg/kg for ease of comparison. Similarly, all surface water results should be reported in µg/L.

Ground Water
1) EPA & NJDEP are concerned with the potential for ground-water contaminant flow into the Salem Canal near the seep area for the following reasons:

a. Ground-water samples collected from monitor wells G05-M06B and G05-M07B have contained significant exceedances (i.e., >GWQS) of VOCs (Figure 18).

b. The G05-M06B and G05-M07B well screens are part of angled borings that are positioned between the sheet pile barrier (SPB) and Salem Canal in the seep area (Figure 3). Consequently, the VOCs detected in these wells is evidential that ground-water contamination is present between the SPB and the canal and is therefore not secured by the SPB.

Please clarify if contamination is entering the Salem Canal and/or Salem Canal sediments via ground-water flow into the canal. The clarification shall include, but not be limited to, ground-water elevation and ground-water quality data that represent wells G05-M06B and G05-M07B. Surface water elevation and surface water quality data from Salem Canal that is coincident with the ground-water elevation and quality data should also be included in the clarification.

2) Monitor wells G05-M06B and G05-M07B shall be included in all future ground-water elevation and ground-water quality sampling episodes and monitoring programs with respect to the evaluation of the Salem Canal and the SPB.

Specific comments

3.3.2 Groundwater Quality- Seep Area: Groundwater results from the most downgradient wells should be compared to the surface water quality standards.

3.3.3 Groundwater Quality- Eastern Portions of Salem Canal: See comments under 3.3.2 above.

4.1.1 Distribution of Potential Site-Related Constituents: Mercury appears to be pervasive throughout Reach 1 and Reach 2. The maximum lead levels are exceedingly elevated. As many of these contaminants are associated with outfall locations, these outfalls may need to be addressed.

4.1.2 Summary of Canal-Wide Sediment Evaluation: The text states that "further ecological evaluation of these data will be conducted as part of the Revised SLERA being prepared for the Salem Canal." EPA & NJDEP concur with this proposal.

5.1 Former Seep Area Evaluation: The text indicates that impacts from the seep area have potential adverse ecological effects. Contaminants associated with the outfalls are also elevated and have potential adverse ecological effects. This statement should be added to the text. The text proposes 4-year monitoring for seep-related constituents. This sampling should take place annually.

Table 4: The table lists Total PAHs at concentrations of 9.7 mg/kg to 22.9 mg/kg, lead at concentrations of 1 ,210 mg/kg to 1 ,390 mg/kg and mercury at concentrations of 1.17 mg/kg to 3.34 mg/kg. These are extremely elevated levels and will need to be addressed.

Figures 23, 24 and 25: These figures indicate elevated levels of contaminants, as noted in the preceding comments, and will need to be addressed.

Sediment sample SC-236-OutT2(0.5-1.0), in the Tidal Reach: The sample contains 118 ppm total PCBs. This high level appears to be a site-related constituent and needs to be delineated and addressed. Please note, EPA would like to discuss the extent of PCBs as a site issue in the coming up September 19, 2017 meeting.

SELs & UTLs: It is noted that, in addition to organics (e.g., PAHs, benzene, and chlorobenzenes), levels of several inorganics in Tidal Reach and Reach 2 sediment samples exceed their Severe Effects Level Ecological Screening Criteria (ESLs) and background UTLs (i.e., chromium, copper, lead, and mercury). These elevated levels need to be addressed.

Appendix A; 3.4 Interim Remedial Action Work Plan and Sediment Supplemental Investigation Work Plan: The wording in the first bullet is confusing and appears to indicate a desired result of "unacceptable impact to surface water." This phrasing should be reworded.

Figures B3, B4a, B4b and B4c; These figures do not report the date of the samples. The date should be provided.

Appendix B7 "Figures B7-6 through B7-9" These figures should indicate the units of analytical results.

Figure B7-7: It is noted that Reach 2 sediment sample SC-189OutF9 (1.0'-2.5') contains the highest concentration of PFAs detected in the Salem Canal. The levels are much higher than those detected in the Reference Area of the canal and appear to be site-related. No sediment benchmark was provided; however, the extent of PFAs in canal sediments remains undelineated.

Figures C-3 through C-6: The figures should identify the "E" data qualifier.

Tidal Reach: Sediment and surface water quality and associated ecological exposure in the Tidal Reach are influenced by both the Salem Canal and the Delaware River. Ecological data from this reach are just as appropriately evaluated with data from the Salem Canal as from data in the Delaware River. For example, sediment or surface water impacts from historic or active outfalls should not be attributed to contaminant tidal influx from the Delaware River. In fact, the opposite cannot be ruled out.

Please submit a written response addressing the above comments within sixty (60) days of your receipt of this letter. We are prepared to discuss the above comments prior to the submittal of the response letter.

If you have any questions, please call Sam Abdellatif, of my staff, at (212) 637-4103.

Sincerely yours,

Ben Conetta, Chief
Corrective Action Section
Hazardous Waste Programs Branch

cc: Helen Dudar, NJDEP-BCM

Message

From: Abdellatif, Sameh [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DA35B30C2C442A802A940056ED76BB-ABDELLATIF, SAMEH]
Sent: 7/28/2017 2:16:36 PM
To: Andrew.S.Hartten@chemours.com
CC: Pavelka, Anne [Anne.Pavelka@dep.nj.gov]; Conetta, Benny [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995e1ef7b652481d89b51a9913171390-Conetta, Benny]
Subject: Chemours 2017 VIMRAR Building 1207.pdf
Attachments: Chemours 2017 VIMRAR Building 1207.pdf

Andrew,

Attached is EPA & NJDEP letter approving Chemours July 20, 2017 VI Mitigation Response Action Report for Building 1207. Hard copies are in the mail.

Thanks

Sam Abdellatif
Hazardous Waste Programs Branch
Clean Air Sustainability Division
U.S. Environmental Protection Agency, Region 2
290 Broadway, 22nd. Floor
New York, NY 10007-1866
Phone: (212) 637-4103

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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JUL 27 2017

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. Andrew S. Hartten
Principal Remediation Project Manager
The Chemours Group
1007 Market Street
P.O. Box 2047
Wilmington, DE 19899

Re: 2017 Vapor Intrusion Mitigation Response Action Report
Building 1207
Chemours Chambers Works, Route 130
Deepwater, Salem County, New Jersey
NJDEP SRP PI# 008221
EPA I.D. Number: NJD 002385730

Dear Mr. Hartten:

The United States Environmental Protection Agency (EPA) and the New Jersey Department of Environmental Protection (NJDEP) have completed their review of the July 20, 2017 Vapor Intrusion Mitigation Response Action Report (VIMRAR) for Building 1207, submitted pursuant to the Resource Conservation and Recovery Act (RCRA) Hazardous and Solid Waste Amendments (HSWA) Permit and the Technical Requirements for Site Remediation at N.J.A.C. 7:26E (Tech Regs). EPA and NJDEP find the submittal acceptable and herby approve the VIMRAR effective the date of this letter.

If you have any questions, please call Sam Abdellatif, of my staff, at (212) 637-4103.

Sincerely yours,

Ben Conetta, Chief
Corrective Action Section
Hazardous Waste Programs Branch

cc: Anne Pavelka, NJDEP-BCM

RA
3/10/09

MP
3/11/09

TK
4/9/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
DuPont Company	)	P-08-508 and P-08-509
	)	
	)	
	)	EPA SANITIZED
	)	
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P-08-508 for the chemical substance [ ] and P-08-509 for the chemical substance [ ] ("the PMN substances") submitted by DuPont Company ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(a) submit to EPA certain toxicity and pharmacokinetics testing on the PMN substance described in P-08-509 at least 14 weeks before manufacturing or importing a total of [ ] kilograms (kgs) of the two PMN substances (or 2 years, whichever comes later, for two of the studies) and [ ] kgs of the two PMN substances combined;

(b) require any workers who may be exposed to wear impervious gloves and distribute the PMN substances to only those customers that agree to require impervious gloves;

(c) require any workers who may be exposed via inhalation to P-08-508 to wear a respirator with a NIOSH Assigned Protection Factor ("APF") of 3000 and distribute to only those customers that agree to require those respirators;

(d) require any workers who may be exposed via inhalation to P-08-509 to wear an appropriate NIOSH-approved respirator and distribute only to customers that agree to require respirators for any workers reasonably likely to be exposed by inhalation;

(e) as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substances in the United States at or below a specified New Chemical Exposure Limit ("NCEL") of 0.01 mg/m3 (based on the current ACGIH TLV/TWA for the ammonium salt of perfluorooctanoic acid ("APFO")) and distribute only to those customers in the United States that maintain this NCEL. (To pursue this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA.);

(f) for operations in the United States, recover and capture (destroy) or recycle the PMN substances from all the process wastewater effluent streams and air emissions (point source and fugitive) at an overall efficiency of 99% and distribute only to those customers that achieve this percentage of efficiency or destruction;

(g) distribute the polymers containing the PMN substances (residuals) at levels not to exceed those specified in this Order and verified using the method in Larsen et al. (2006);

and

(h) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): specific chemical identity, production volume, manufacturing process and sites, processing, use, and other information

Chemical Identities:

Specific: **P-08-508** [ ]

CAS no.: [ ] and **P-08-509** [

] CAS no.: [ ].

Generic chemical identity: **P-08-508**– Perfluorinated aliphatic carboxylic acid and **P-08-509**–Perfluorinated Aliphatic Carboxylic Acid, Ammonium Salt

Use:

Specific: **P-08-508**-[

] and **P-08-509**-[

] Intended to replace [

]

Generic: **P-08-508**-Intermediate for polymerization aid, **P-08-509**-polymerization aid

Maximum 12-Month Production Volume: **P-08-508**-[ ] kgs, **P-08-509**-[ ] kgs

Test Data Submitted with PMN: Physical and Chemical characteristics; Determination of the Dissociation Constant (salt); Determination of Water Solubility and Vapor Pressure; Biopersistence and Pharmacokinetic Screen in the Rat; In Vitro Trout Hepatocyte

Bioaccumulation Screen; Thermal Decomposition Study results

Toxicity: Acute oral toxicity, up-and-down procedure and Acute Oral Test (rats and mice); Approximate Lethal Dose (ALD) in rats and mice; Acute Dermal Toxicity in Rats; Approximate Lethal Dose (ALD) by Skin Absorption in Rabbits; Local Lymph Node Assay (LLNA) in Mice; Acute Eye Irritation in rabbits; Acute Dermal Irritation Study in Rabbits; 7-day Repeated Dose Oral Toxicity in Rats and Male Mice; 28-Day Repeated Dose Oral Toxicity Study in Rats and Mice; Corrositex in vitro test; Combined Two Week Inhalation Toxicity and Micronucleus Studies in Rats-Transformation Byproduct. In Vitro Micronucleus and Chromosome Abberration Assay in Mouse Bone Marrow Cells; In Vitro Rat Hepatocyte Screen, Bacterial Acute Mutation test; Determination of permeabillity coefficient (Kp) using a static in vitro diffusion cell model; In Vitro evaluation for Chromosome Aberrations in Human Lymphocytes-transformation byproduct

Mutagenicty test in Salmonella Typhimurium-transformation; byproduct; Combined two week inhalation toxicity and micronucleus studies in -transformation byproduct; Water solubility, vapor pressure, and octanol water partition coefficient and other p-chem properties of transformation byproduct; Thermal Transformation Byproduct

Ecotoxicity/Fate: Acute toxicity to fish (Rainbow trout), daphnia, and algae; Ready Biodegradability Study; Activated Sludge Respiration Inhibition Test; and Assessment of Hydrolysis as a Function of pH

In general, the test substance was the salt (509), except for some acute studies, pharmacokinetics, and mutagenicity where the test substance was both the acid (508) and the salt (509) or as noted below. For a complete listing, see the PMN.

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substances, based on the information currently available to the Agency.

Human Health Effects and Fate Summary:

EPA has concerns that these PMN substances will persist in the environment, could bioaccumulate, and be toxic ("PBT") to people, wild mammals, and birds. EPA's concerns are based on data on the PMN substances, analogy to other [ ] chemicals, and to perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS") which are both currently under review by EPA for PBT concerns. Some [ ], PFOA, and PFOS are expected to persist for years in the environment. Biodegradation and photolysis tests of some analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples.

Based on test data on structurally similar [ ] chemicals and data on the PMN substances themselves, EPA has human health concerns for the PMN substances. The PMN substances are expected to be absorbed by all routes of exposure. The PMN substances show low acute oral toxicity ($\geq$ 3400 mg/kg). The acute dermal toxicity study with P-08-509 shows low acute dermal toxicity (>5000mg/kg). The PMN substance P-08-508 is expected to be highly irritating or corrosive. There is high concern for eye irritation for both PMN substances.

The PMN substance P08-509 was tested in a 28-day repeated dose study in rats and mice. In the rat study, the doses were 0, 0.3, 3, and 30 mg/kg/day in males and 0, 3, 30, and 300 mg/kg/day in females. The EPA reviewer set the NOAEL in males at 0.3 mg/kg/day based on dose related trends and statistical significance of change in hematologic findings (decreases in red blood cell counts, hemoglobin, and hematocrit in males), increase in clinical chemistry, increases in absolute and relative organ/body and liver weights. Histopathologic findings in the liver included minimal or mild hepatocellular hypertrophy in males at 3 and 30 mg/kg/day. In this study in rats, the EPA reviewer set the NOAEL at 30 mg/kg/day in females based on increased liver weights and liver pathology as hepatocellular hypertrophy in females given 300 mg/kg/day. The investigators concluded that the NOAELs were 30 mg/kg/day in males and 300 mg/kg/day in females, stating that all changes in treated groups are within historical control ranges at the testing facility and as adaptive responses.

In the mouse study, the doses were 0 (vehicle control), 0.1, 3, or 30 mg/kg/day of test substance in deionized water by gavage daily for 28 days with terminal sacrifice on day 29. In addition, 10 male and female mice were similarly treated with 0 (vehicle control), 30 (males), or 300 (females) mg/kg/day and killed after 28 days of recovery following treatment.
The EPA reviewer set the NOAEL at 0.1 mg/kg/day based on signs of anemia and liver effects at higher dose levels. The investigators placed the NOAEL at 0.1 mg/kg/day in males and 3 in females.

A related [ ] substance was also tested in a 28-day study in rats. The doses were 0, 5, 25, and 100 mg/kg/day with a NOAEL of 5 mg/kg/day and effects on the liver and kidney at 25 and 100 mg/kg/day. A single dose pharmacokinetic study was conducted in the rat and the

monkey. Male and female results were similar. Toxicity studies on some [ ] have shown systemic toxicity in animals at levels as low as 0.13 mg/kg in a 90-day oral toxicity study.

Some data exists on the transformation product [ ] and [ ] in combined two week inhalation toxicity and micronucleus studies. Doses were 0, 5,000, 25,000 and 175,000 ppm. The NOAEL was determined to be 175,000 ppm. No systemic toxicity relevant to humans was exhibited for [ ]. For [ ], increased absolute and relative liver weights were seen in this limited study at 25,000 ppm. Mutagenicity in this study was negative.

Several mutagenicity studies were conducted on both PMN substances, P-08-508 and 509. They were not gene mutagens in two species of prokaryotes, and not inducers of DNA effects in mammalian cells *in vivo*. They were chromosome mutagens in mammalian and human cells in culture, but not in mammals *in vivo*. The EPA reviewer concluded that the positive data on the PMNs for *in vitro* chromosomal aberrations in mammalian and human cells are of some concern. However, the negative responses for *in vivo* chromosomal effects as micronuclei and as chromosomal aberrations, and for induction of DNA effects, alleviates that concern. No additional mutagenicity testing is recommended.

For chronic and carcinogenic effects, no information was submitted. EPA believes that a 2-year Chronic Toxicity/Carcinogenicity study (OPPTS 870.~~3100~~, OECD 453) is needed.

Pharmacokinetic studies were conducted in rats. Groups of 3 male and 3 female rats were dosed via single oral gavage with either 10 or 30 mg/kg of the PMN substance P-08-508 (98%) and P-08-509 (84.5%). Blood samples were taken before dosing and periodically thereafter up to 168 hours (7 days) after dosing. In addition, fat and liver samples were taken at terminal sacrifice. Samples were analyzed for the parent compound using HPLC/MS with a level of

quantitation (LOQ) at 20 ng/ml. Clearance times were calculated for the 2 doses for males and females as follows:

	10 mg/kg (508)	30 mg/kg (508)	10 mg/kg (509)	30 mg/kg (509)
Male	28 hr	22 hr	12 hr	22 hr
Female	8 hr	4 hr	4 hr	8 hr

The Company has done some limited biomonitoring in workers and site monitoring. EPA has reviewed the biomonitoring and concluded that samples did not take place over a long enough period of time to see if accumulation occurred and that the limit of detection was not sensitive enough to draw any conclusions at this time.

Toxicity studies on the analogs PFOA and PFOS indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the docket EPA-HQ -OPPT-2003-0013. Additional information about PFOA and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226). Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling 202/566-0280 or sending an email request to oppt.ncic@epa.gov.

The data on the PMN substance and some other data indicate a different and less toxic profile for the PMN substances than for PFOA and PFOS. However, based on: 1) the persistence of the PMN substances, 2) the toxicity of the PMN substances and some of the [ ] analogs, and 3) the possibility or likelihood that this substance may be used as

a major substitute for a major use of PFOA, EPA believes that more information is needed on the toxicity and pharmacokinetics of the PMN substance P-08-509 that will be applied to the characterization of both PMN substances.

EPA believes that additional pharmacokinetic, reproductive, and long-term toxicological testing on the PMN substance P-08-509 in animals is warranted. EPA will require at a certain production volume that a modified reproductive test (OECD 421, modified) be conducted. The modifications for the reproductive test include: (1) increase the parental sample size to 20; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional); (7) at weaning one pup/sex/litter shall be randomly selected to follow until sexual maturation; and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation). In addition, the Company will also conduct Repeated Dose Pharmacokinetics and Metabolism testing (OPPTS 870.7485); a Combined Carcinogenicity/Chronic Toxicity test (OPPTS 870.4300/OECD 453); and an Avian Reproduction test (OECD 206, OPPTS 850.2300).

Environmental Effects Summary:

EPA expects the PMN substances to be highly persistent in the environment. In addition, they may be bio-accumulative or biopersistent based on the predicted log Koc and because some

related substances show evidence of biopersistence. No short-term ecotoxicological concerns were raised for the PMN substances. Reported results in acute toxicity tests in fish (rainbow trout), Daphnia magna and green algae were: fish–96 hr LC 50>96.9 mg/l; Daphnia magna 48 hr EC50 > 102 mg/l; and 72 hr EC50>106 mg/l. However, there is high concern for possible environmental effects over the long-term. As stated previously, the analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species. The presence in the environment and toxicological properties of PFOA continue to be investigated. EPA believes development of additional data is warranted. EPA will require at a certain production volume that a Fish Early Life Stage Toxicity test (OPPTS 850.1400), a Daphnid Chronic Toxicity test (OPPTS 850.1300), and an Avian Reproduction test-Bobwhite Quail (OPPTS 850.2300) be conducted.

Exposure and Environmental Release Summary:

These PMN substances will be manufactured by [

]. P-08-509 will be used as a polymerization aid in the manufacture of [ ].

Several points of exposure and release were submitted and evaluated for these PMN substances. Doses were calculated for dermal and inhalation exposure to P-08-508 from loading and unloading drums and sampling. Inhalation exposures are to vapors with up to 20 workers potentially exposed. EPA estimates that these quantities could be between 3.8 mg/day (typical) to 230 mg/day (worst case). There may be dermal exposure to a liquid containing P-08-508. For P-08-509, manufacture and use were assumed at up to 3 sites (2 DuPont sites and one potential customer site). According to the Company, only one site will be used at a time. At these sites, the material will be unloaded and charged to various process vessels, such as a blend tank or a polykettle. Due to the low vapor pressure of P-08-509, only dermal exposure was evaluated. Based on the possibility of inadvertent exposure at low levels, the Order requires that any person who is reasonably likely to be exposed by inhalation to the PMN substance P-08-509 to wear an appropriate NIOSH-approved respirator. EPA has established for both PMN substances a New Chemical Exposure Limit ("NCEL") at 0.01 mg/m3, the Threshold Limit Value ("TLV") currently recommended for APFO by the ACGIH in the United States, in order to "level the playing field" and allow the substitution of the PMN substance P-08-509 into the marketplace. EPA believes that this limit should be adequate for the PMN substances based on current information. If this ACGIH level were to change or there is data on the PMN substances that EPA believes warrants a change, the NCEL may be changed in order to correspond with the new level or data.

Releases to the environment were estimated to water and to air (fugitive) and to air via incineration. Based on submitter information, the Company currently collects the waste containing the PMN substances and sends the waste to an off-site RCRA incinerator. In the future, the Company intends to develop and use methods to recapture and/or recycle the substances, but is not now doing so. EPA requires in the attached Consent Order that the substances be recovered, recycled and/or destroyed at levels achieving 99% efficiency. EPA will require that the Company directly sell the substances only to customers, if any, that achieve comparable recovery or destruction. The Company shall distribute the PMN substance, P-08-509 in polymers, aqueous or solid, so that the residual P-08-508/509 cumulative total [

] are below 200 ppb level using the ASE method developed by Larsen et al. (The Analyst 2006 p. 1105) with the level of quantification (LOQ) for the standard solution at 0.5 ppb. If non-heat treated solid polymer is distributed then the substance cannot be further distributed, until it is sufficiently heat treated. The Company should make every effort to minimize or prevent any release to the environment of these substances. If any new uses of the substance are found, the Company shall find ways to recover and/or recycle the substance to comparable levels. Fugitive releases may be of particular concern.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substances. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA,

that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substances.

B. In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to human health and the environment.

C. In light of the estimated production volume of, environmental release of, and human exposure to, the PMN substances, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substances will be produced in substantial quantities for a potential PBT substance, may reasonably be anticipated to enter the environment in substantial quantities for a potential PBT substance, and there may be significant (or substantial) human exposure to the substances.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will

remain in effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

Fate and Physical/Chemical Properties information as follows:

Physical/Chemical Property Testing	**OPPTS or OECD Guideline**
UV visible absorption	OPPTS 830.7050 or OECD 101
Hydrolysis as a function of pH	OPPTS 835.2130 or OECD 111

Environmental Fate Testing	**OPPTS or OECD Guideline**
Modified Semi-Continuous Activated Sludge (SCAS) with Analysis for degradation products	OPPTS 835.5045, OPPTS 835.3210 or OECD 302A
Aerobic and Anaerobic Transformation in Soil	OECD 307
Aerobic and Anaerobic transformations in Aquatic Sediment Systems	OECD 308
Direct Photolysis in Water (if wavelengths >290 nm are absorbed)	OPPTS 835.2210
Indirect Photolysis in Water	OPPTS 835.5270
Phototransformation of Chemicals on Soil Surfaces	OECD Jan. 2002 Draft
Simulation test-Aerobic Sewage Treatment (Activated Sludge Units)	OECD 303A
Anaerobic biodegradability of organic compounds in digested sludge	OECD 311
Fish Bioconcentration test	OPPTS 850.1730

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances [

] (P-08-508) and [

] (P-08-509) ("the PMN substances") in the United States by DuPont Company ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substances

for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substances when they are produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when they are manufactured, pursuant to any of the exemptions in 40 CFR

720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Any information on the PMN substances which reasonably supports the conclusion that the PMN substances presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results. Because the Chronic Daphnid Toxicity study and the 90-day toxicity study enumerated below were begun before the execution of this Order the requirement for submission and approval of the protocols for these two studies only is waived.

(d) Triggered Testing Requirements. (i) The Company is prohibited from manufacturing or importing the PMN substances beyond the following aggregate manufacture and import volumes of both PMN substances combined ("the production limits"), unless the Company conducts the following studies and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Guideline
[ ] kilograms *	1) Repeated dose Metabolism and Pharmacokinetics rats and mice	OPPTS 870.7485
	2) Modified 1-generation Reproduction study	OECD 421, modified, per (iv) below

	3) Avian Reproduction-Bobwhite Quail	OPPTS 850.2300
	4) Fish Early Life Stage Toxicity	OPPTS 850.1400
	5) Daphnid Chronic Toxicity	OPPTS 850.1300

*An alternate Production Limit for studies 1 and 2 only is two years from the date of commencement of nonexempt commercial manufacture of either PMN substance, or [ ] kilograms, whichever comes later.

[ ] kilograms	6) 90-day toxicity study	OPPTS 870.3100 (OECD 408)
	7) Chronic toxicity/ carcinogenicity study	OPPTS 870.4300 (OECD 453)

(ii) the test substance shall be the substance described in P-08-509;

(iii) EPA recommends that the Company conduct the pharmacokinetics testing first to confirm species acceptability and to provide a reliable half-life for these substances;

(iv) The modifications for the 1-generation reproduction study (study 2 above) are: 1) increase the parental sample size to 20; 2) the duration of the study shall be extended to until the pups have reached sexual maturation; 3) parental males shall be dosed for 10 weeks prior to mating; 4) dosing of the parental animals shall be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; 5) pup body weight shall be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals; 6) litter size can be

standardized to 4 pups/litter on lactation day 4 (optional); 7) at weaning one pup/sex/litter shall be randomly selected to follow until sexual maturation; and 8) the time of sexual maturation shall be recorded (i.e. vaginal opening and preputial separation).

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal,

the Company may continue to manufacture and import the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the

Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1)Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with

subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substances, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture,

import, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substances at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substances), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substances through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance

becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Specific Dermal Protective Equipment. The dermal personal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs and torso. Clothing in this subparagraph (a)(2)(iv) need not be tested or evaluated under the requirements of subparagraph (a)(3)

(3) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the

chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time (or versus time), and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substances.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substances alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance, P-08-508, in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an Applied Protection Factor ("APF") of 3000 from the respirators listed in subparagraph (a)(6) of this section. All respirators must be used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory

protection program under the OSHA requirements in 29 CFR 1910.134.

In addition, each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance P-08-509 must be provided with and wear an appropriate NIOSH-approved respirator.

(5) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

(i) Particulate (including solids or liquid droplets),

(ii) Gas/vapor (all substances in the gas form), or

(iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are both present; a good example is paint spray mist, which contains both liquid droplets and vapor).

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for P-08-508 in subparagraph (a)(4) of this section:

–a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full face piece.

NEW CHEMICAL EXPOSURE LIMIT

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substances by

inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the PMN substances, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substances by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit ("NCEL") for the PMN

substances is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substances is as follows:

(i) Time-Weighted Average ("TWA") Limit. The Company shall ensure that no person is exposed to an airborne concentration of both PMN substances combined in excess of 0.01 mg/m3 (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift ("NCELn") shall be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit ("PEL") specifically applicable to these PMN substances and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL shall automatically become null and void. However, the requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the PMN substances.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical

method for the PMN substances, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(II), (4)(v)(II), (8), (9), and (10). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substances which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN # _____," after-which the correct PMN number for this chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company shall have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the PMN substances, in accordance with the other requirements in this subsection (c)(3). It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and

from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substances must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 CFR Part 792. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company shall collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples

pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company, and the other shall be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment B - Statistical Analysis of NCELs Analytical Method Verification Results.) The arithmetic mean of each set of six samples must be within 10% of the overall arithmetic mean of the two sets of